Marketing of drugs having adverse effects

2869. SHRI RAJNI RANJAN SAHU: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that a number of drugs being marketed in India are proved to produce adverse reactions such as anti-inflammatory, anti-coagulants, corticosteroids, antineoplastic agents and others, if so, names of those drugs;

(b) whether it is also a fact that chloroquine and Diethylstibestrol given to pregrant mother can produce dangerous effect to the child, if so, what steps have been taken for their precautions; and

(c) whether it is a fact that: Hydroxyquinoline compounds drugs have proved to be very toxic, if so, why such drugs have been allowed to be marketed in our country?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) Every drug has desirable therapeutic effect and undesirable side effect-adverse reaction. Anti-inflammatory drugs such as Aspirin, Prenylbutazone, Oxyphenbutazone, Ibuprofen, Naproxen, Ketoprofen, Diclofenac Sodium, Pyroxicam, etc. generally produce gastritis, gastric bleeding/ulcer as side effects and some drugs may also produce blood disorders. Similarly, anti-coagulants like heparin and coumarin derivatives may produce excessive bleeding in sensitive population as an adverse reaction, Dexamethasone, Hydrocortisone, etc. which are life saving drugs can produce on continued treatment deposition of fat under the skin of the face and clavicle (moon face) osteoporosis in long bones, etc. as adverse reactions. Antineoplastic drugs i.e. anti-cancer drugs like Vincristine, Vinblastic, etc. on continued treatment can produce falling of hair, blood disorders etc.

(b) Like many drugs Chloroquine and Diethylstibestrol can produce adverse effects on the children if these drugs are given to pregnant mothers. These drugs are contra-indicated and the medical profession are aware of it.

(c) Experts have considered Hydroxyquinoline group of drugs useful for the treatment of diarrhoea and did not recommend withdrawal.

Harmful effect of Imodium and Lomotil

2870. SHRI RAJNI RANJAN SAHU: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that Imodium and Lomotil have proved to be potentially harmful and World Health Organisation have made certain recommendations in this regard; and

(b) if so, details of the recommendations and the action taken by the Government?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) and (b) Imodium, a brand of Loperamide and Lomotil, a brand of Diphenoxylate Hydrochloride, both anti-diarrhoeal drugs, by virtue of their pharmacological action may cause Central Nervous System stimulation as side effects particularly in children and accordingly. WHO and other advisory body have recommended not to use these drugs in children. In India also, use of these drugs are contra-indicated for children.

Withdrawal of marketing permission for the vaccine combinations

2871. SHRI RAJNI RANJAN SAHU: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to refer to the reply Unstarred Question 441 given in the Rajya Sabha on the 29th July, 1987 and state:

(a) when were the instructions sent to FDA, Maharashtra to withdraw the permission granted for marketing of the vaccine in combination with Polio vaccine;

(b) whether FDA, Maharashtra has taken action in the matter; and

(c) if so, the details thereof?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) Instructions were issued to FDA, Maharashtra on 3-6-87 to withdraw permission granted for marketing of quadruple vaccine (combination of DPT and Polio).

(b) and (c) FDA, Maharashtra has already taken action to withdraw the permission to market the quadruple vaccine.

Substandard medicines

2872. SHRI RAJNI RANJAN SAHU: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to refer to Unstarred Question 333 given in the Rajya Sabha on the 29th July, 1987 and state:

(a) whether it is a fact that 20 per cent to 30 per cent medicines have been found to be sub-standard;

(b) if so, what steps have been taken to curb this evil; and

(c) what are the details of action taken against the drug companies whose samples were found to be of sub-standard quality?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) to (c) The percentage of sub-standard drugs reported during the year 1983-84, 1984-85 and 1985-86 are as follows:—

Years	No. of sample tested	No. of samples found sub-standard	Percentage of Sub-standard
1983-84	16768	2535	14 98%
1984-85	18504	3532	19 08%
1985-86	19035	2705	14 20%

Under the provisions of the Drugs and Cosmetics Rules whenever any sample of drug is found to be sub-standard actions like withdrawal of batch from the market etc., cancellation/suspension of Licences and prosecution of the firm depending upon the nature of test reports are taken by the State Drugs Controllers who are the Licensing Authorities.

Consumption of Oxyphenbutazone

2873. SHRI RAJNI RANJAN SAHU: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to refer to Starred Question 48 given in the Rajya Sabha on the 29th July, 1987 and state:

(a) the names of medical experts consulted about continuous consumption of Oxyphenbutazone and Phenylbutazone alongwith the names of institutions to which attached;

(b) what were the basis of their opinion and the grounds for differing with the World reports; and

(c) what are the names of other drugs being marketed in India for the treatment of Ankylosing spondylitis and gauty arthritis and whether any of these have been withdrawn by any country?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) The expert bodies consulted on